



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Request for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels and Request for Notification from Consumer Organizations Interested in Participating in the Selection Process for Nominations for Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for current vacancies and for those that will or may occur through December 2013.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see

ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be sent electronically to CV@OC.FDA.GOV, by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., WO32 rm. 5129, Silver Spring Maryland 20993-0002, or by fax to 301-847-8640. Information about becoming a member of an FDA advisory committee can be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Dornette Spell-LeSane, Advisory Committee Oversight and Management Staff, Food and Drug Administration, White Oak Bldg 32 10903 New Hampshire Ave., rm. 5129, Silver Spring, MD 20993-0002, 301-796-8224, email: dornette.spelllesane@fda.hhs.gov.

For questions relating to specific advisory committees or panels, contact the following persons listed in table 1:

Table 1.—Committee Contact

Contact Person	Committee/Panel
Stephanie Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg 31, 10903 New Hampshire Ave., rm. 2408, Silver Spring, MD 20993-0002, 301-796-3693, FAX: 301-847-8533, email: Stephanie.Bregansky@fda.hhs.gov .	Anesthetic and Analgesic Drugs
Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg 31, 10903 New Hampshire Ave., rm. 2408, Silver Spring, MD 20993-0002, 301-796-9014, FAX: 301-847-8533, email: Diane.Goyette@fda.hhs.gov .	Anti-Infective Drugs
Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg 31, 10903 New Hampshire Ave., rm. 2408, Silver Spring, MD 20993-0002, 301-796-0063, FAX: 301-847-8533, email: Nicole.Vesely@fda.hhs.gov .	Cardiovascular & Renal Drugs
Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak Bldg 31, 10903 New Hampshire Ave., rm.	Pulmonary Allergy Drugs

2528, Silver Spring, MD 20993-0002, 301-796-0889, FAX: 301-847-8533, email: Cindy.Hong@fda.hhs.gov .	
Jamie Waterhouse, Center for Devices and Radiological Devices, Food and Drug Administration, White Oak Bldg 66, 10903 New Hampshire Ave., rm. 1611, Silver Spring, MD 20993-0002, 301-796-3063, FAX: 301-847-8116, email: Jamie.Waterhouse@fda.hhs.gov .	Circulatory System Devices

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

Table 2.—Committee Description, Type of Consumer Representative Vacancy, and
Approximate Time Needed

Committee/Panel/ Areas of Expertise Needed	Current & Upcoming Vacancies	Approximate Date Needed
Anesthetic and Analgesic Drugs-- Knowledgeable in the fields of anesthesiology, analgesics (such as abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties.	1- Voting	Immediately
Anti-Infective Drugs-- Knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties.	1 – Voting	December 1, 2013
Cardiovascular and Renal Drugs-- Knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics.	1 – Voting	July 1, 2013
Pulmonary Allergy Drugs-- Knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics.	1 - Voting	June 1, 2013
Circulatory System Devices-- Knowledgeable in the safety and effectiveness of marked and investigational devices for use in the circulatory and vascular systems.	1 Non-Voting	July 1, 2013

I. Functions

A. Anesthetic and Analgesic Drug Products

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in

anesthesiology and surgery and makes appropriate recommendations to the Commissioner of Food and Drugs.

B. Anti-Infective Drugs

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

C. Cardiovascular and Renal Drugs

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

D. Pulmonary-Allergy Drugs

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

E. Certain Panels of the Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area; advises on the classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Criteria for Members

Persons nominated for membership as consumer representatives on the committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee;

serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committee on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see ADDRESSES) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Potential candidates will be required to provide

detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

All nominations should include: a cover letter; a curriculum vitae or resume that includes the nominee's office address, telephone number, and email address; and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations also should specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination and is willing to serve as a member of the advisory committee or panel if selected.

The term of office is up to 4 years. FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

Dated: June 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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